

EXHIBIT 185

December 13, 2017 Suspicious Order Monitoring Workshop

December 13, 2017 Work Shop Agenda

830-845	Introductions
845-1045	Terry Woodworth: History of Suspicious Order Monitoring, the Regulations vs Expectations
1045-1100	Break
1100-1200	Michele Dempsey: Current JOM program, TEVA benchmark Terry Woodworth: Industry Best Practices.
1200-100	Lunch
100-300	Open discussion on potential enhancements to our program

Prep Stakeholder Interviews:

- **Brad Hummel** - KDC leader who will be involved with Louisville DEA when they come to inspect Friday, December 1, 2017 9:00 AM-9:30 AM
- **Tracy Guldan** – Quality leader taking ownership of the DEA Compliance program Friday, December 1, 2017 2:00 PM-2:30 PM
- **Ursula House Siberry/John Leahy** – value Stream leaders for Controlled Substances Monday, December 4, 2017 4:00 PM-4:30 PM
- **Frank Mashett** – Trade Monday, December 4, 2017 10:00 AM-10:30 AM
- **Belinda Corum** – CSC Compliance Monday, December 4, 2017 1:00 PM-1:30 PM
- **Tom Stukane** – Regulatory Law Compliance Monday, December 4, 2017 3:30 PM-4:00 PM
- **Andres Lopez** – Regional Director Customer Services Monday, December 4, 2017 8:30 AM-9:00 AM
- **Nguyen Tran/Scott Trembley** - Established Products Commercial Product Directors for Controlled Substance products Monday, December 4, 2017 11:00 AM-11:30 AM
- **Marlene Shea** – Esketamine regulatory law Wednesday, December 6, 2017 9:00 AM-9:30 AM
- **Pat Hatfield, Raffaela Figliano, Debbie Sniscak** – HealthCare Services – December 12, 2017
- **John Crenshaw** – KDC/FDC leader Monday, December 18, 2017 12:00 PM-12:30 PM
- **Ed Schreiber, Tom Stukane** – December 20, 2017 10:00AM-11:00AM
- **Gregg Ruppersberger** - Director of Marketing – Mood (Esketamine) No open time on calendar – need to follow up

Comment [SB1]: Reordered by interview date and added HCS interviews the day before the workshop. I hope I did not mess it up.

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Workshop Attendees:

- Terry Woodsworth – present at FDC
- Tracy Guldan – phone
- Ursula House Siberry – present at FDC
- John Leahy – present at FDC
- Belinda Corum – phone
- Michele Dempsey – present at FDC
- Brian Strehlke – present at FDC
- Andres Lopez – present at FDC
- Nguyen Tran – phone
- Scott Trembley – phone
- Ben Laing – present at FDC
- Mike Morand – present at FDC
- Raffaela Figliano – phone
- Pat Hatfield – phone
- Debbie Sniscak – present at FDC
- Beth Briest – present at FDC

Opportunities with current Order Monitoring Program Discussed at 12/13/17 Workshop

I. Algorithm

1. The current monitoring report in SAP BW runs once a day, assumes all orders have been placed for the day. There have been instances where Controlled Substance orders (Sch III-V) are placed after the report is run (3:45PM) and there is the potential that an order can be released the next morning without being monitored in the program.
 - Current Remediation process- If order time stamp is after 230, the order is held (tramadol, TWC orders) on business manager hold until the next day so the order can run through the algorithm.
2. The current monitoring report is based on three times the customer's 12 month rolling weekly average of shipments.
 - The report rolling average will not show slow increases in order patterns or if a new customer starts at higher levels vs similar size customers.
 - The report does not take into consideration multiple orders in one month – the accumulation effect exceeding the total for the month. It compares the one order against the historical 3x12 month week average.
 - The current 3x 12-month moving average was based on DEA feedback for List 1/precursor chemical orders. Future state monitoring program needs to be more current to Industry practice.
3. Current BW report (algorithm) measures orders by NDC number (SKU) not drug class (total fentanyl for example) or consolidated customer (just ship to address). and does not track total gram base of controlled substance to the consolidated or individual registrant. For example, we do not follow how much methylphenidate (Concerta) is shipped to all HD Smith locations or to the individual locations. We track how much of each SKU is shipped to a

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Comment [DM3]: Any time we need to have a review done each morning by personnel leads to potential of error. The current remediation is not the preferred long-time solution.

Comment [SB4]: Consolidating drug class and customer locations should go a long way towards eliminating false positives in the report.

Comment [DM5]: Agree! Can't tell you how many investigations are done because a customer hasn't ordered a particular strength in the last 12 months.

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location. The team aligned that in the future, our software should track by drug code (in grams base not EA) and consolidate customer locations.

4. The BW ordering monitoring report is working as designed – meaning capturing all the orders; However, there is no way to go into the BW report to see what orders were reviewed and confirm that a particular order was checked.
5. The current report does not compare customers against similar wholesalers and their ordering patterns. The team aligned that in the future, our software should differentiate by customer type (large, medium, small wholesaler).

II. Processes

1. Investigation: When an order hits the monitoring report, DEA Compliance should review the investigation and then make the decision on whether the order should ship.
 - a. Those supporting the order (Planning Channel Ops, Trade, Customer Service) need to complete the documented investigation and ensure all areas are covered in the documentation.
 - b. If Channel Ops team knows an order is larger than typical – they should communicate in advance so documentation can be prepared before the order is placed and run through the order monitoring program.
2. Ordering: Customers enter Schedule II products by themselves. Sch III-V are not separated from non-CS products upon Customer entry of the order. Consider if putting on business manager hold impacts the non-CS orders. Product is held, but rest of order can ship. Is the sales order on hold? Follow up.
3. Ordering: Current Customer Service in Centennial building does not receive mail directly. All 222s and paper orders go to Building 425 where Channel Ops team resides. Gets sorted and J&J employee/Security brings it over between 11:30-2. In the past went directly to FDC. Envelopes by 10am every day.
 - a. Making sure orders are in by 230 for paper/manual orders can be a challenge if FedEx or UPS is late, or paperwork does not get to Centennial building in time.
4. Ordering: The existing SOM program is dependent on Human interaction.
 - a. Every shipment order time stamp is checked manually against the SAP monitoring report to ensure it was run through the program (confirmed Sch II are checked – gap with schedule III-V).
 - b. The same restrictions on order placement for Schedule IIs is not used for Sch III-V. There is no flag in the system to prevent orders from being placed throughout the day for scheduled products.
 - c. SAP allows orders to be placed anytime. There is no hardstop with the monitoring report. The future state program should have thresholds embedded into master data such that when an order is placed, the person who enters it is immediately notified that the order is not typical.
5. Compliance Review: Reviews are done monthly between DEA Compliance and Customer Service. Internal metrics are reviewed; however, an opportunity exists to have a broader review with management during the QSMR. More visibility throughout the supply chain is needed – provide information to PM for VST review.

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Comment [DM7]: Currently when an atypical order is identified, customer service emails DEA Compliance and that is all. DEA compliance has to ask the questions, collect the data, compile into a document to save on the sharepoint. We are asking the owners of the information to do the documentation and then DEA compliance reviews and makes final decision – will explain more about this with you later.

Comment [SB8]: Does this work with consolidated locations and drug codes?

Comment [DM9]: Did I say we would consolidate locations? It will work with drug codes, not sure we want to consolidate all locations

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Comment [DM11]: I think at this time the future state has not been defined and approved yet. IT workshop in January to define whether the threshold process will work.

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Comment [DM13]: The workshop attendees did not know about the monthly reviews and thought we needed to better communicate the outcomes and metrics.

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Comment [DM15]: PM – Product Management VST – Value Stream Team

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6. **Training:** Currently training is performed through presentations by Trade and Customer service. There is an opportunity to formalize the training program, with specific training for each department involved in the program. The team recommended the following:
 - Customer Service training should include all relevant SOPs including out of trend order investigation and the overall program training.
 - Channel Ops Planning training should include all relevant SOPs, how they support investigations, how they need to communicate in advance customer demand changes that will impact the monitoring program, overall program training. Planning interacts with wholesalers and supports the setup of new customers. They need to provide the information needed to approve new customers into the SOM program.
 - Trade training should include overall program training and how they support investigations. Trade also engages the wholesalers and may need to support obtaining questionnaires/documentation on new customer. Trade needs to understand the 867 data and 852 data from a SOM perspective to support the program.
 - Compliance (Quality/CSC) will ensure training is up to date and is perform for all functions. Their training will include order release process, compliance periodic reviews and overall program.
 - Management (leadership at JOM) training needs to include the overall program knowledge, impact the program has on resources and the business.
 - Distribution Center training – they should have high level understanding of SOM and the requirements to have a program in place for scheduled products. Schedule material handlers are the first to report out on out of trend shipments.
 - JOM Compliance Wire training deck – update to include SOM
7. **Procedures:** A review of all relevant SOPs is needed to ensure that it is clearly stated that the current SAP report and future report is a monitoring tool, it is not the SOM program. The SOM program is a series of processes:
 - monitoring tool that lets us know about an out of trend order,
 - the investigation process for the out of trend order;
 - the compliance review/approval/denial of the order;
 - the periodic review and report out of orders, threshold limit review, trends, metrics, google alerts,etc.
 - Documented procedures and training to support the program
8. **Order Monitoring:** Identify how chargeback/EDI Value Centric data could be routinely used to identify potential suspicious trends at the pharmacy/patient level. Need to discuss how we can use 852, 867 and Intrachain data for follow up investigations on atypical orders as well.
 - 867 data provides visibility of sales past the wholesaler. Some data is blinded (Rite Aid, CVS won't let you see pharmacy information).
 - Intrachain is a competitor of Value Track that takes all the 867 field data and unbinds it so we can see buying patterns. Commerical Excellence (Glen Moering, Cherlyn) can explain what data we receive and if we are tracking sales.

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- 852 data tells what is ordered at the NDC level. Transmits daily from the distributors. Days of supply, weekly sales average is data currently used. There is always a 1 day lag in data.

Action Items from Workshop

- Procedure updates:
 1. Customer Service: in DS-WI-3824 Remove "unusual" from all procedures and replace with either "questionable" or "out of trend" or "atypical".
 2. Customer Service: in DS-WI-3824 revise to require customer follow up for all atypical orders. Remove references to big three. Have follow up done before notifying CSC group.
 3. Customer Service: If we ever have a true suspicious order, which requires reporting, procedure should require full examination of other orders by the same purchaser and evaluation of appropriateness of future shipments.
 4. Michele: ZATP report mentioned on the Visio process map is no longer used. It is referenced in flow chart for order processing but not in any SOPs. Remove from Visio flow
 5. Ben: Questionnaires should be reviewed with wholesalers and updated on a periodic basis. Not just filled out once and not updated. Perhaps during contract reviews request new questionnaire. Please discuss with Trade/Channel Ops and determine which SOP needs to be revised to
 6. Customer Service DS-WI-30472: New customer SOPs need to be reviewed and updated to reflect the process with ownership. How new customers are approved needs to be explained in a document.
 7. Beth: DS-SOP-1251 Master Data SOP does not list who does what in collecting new customer information. Also "5.2.1.1 Customer must comply with Quality Requirements in order to be considered a direct Distributor. Refer to DS-SOP-15597: Quality Requirements for Distributor Selection, Qualification and Approval and DS-SOP- 15598: Quality Monitoring and Disengagement Requirements for Distributors" references obsolete BQ procedures.
 8. Belinda/Customer Service: in DS-WI-3824 need to provide guidance on how to communicate Suspicious Orders to DEA (who, how and when), include also reporting to relevant state regulatory agencies as required.
 9. Belinda: Review diversion policy – include SOM wording and post at DCs.
 10. Belinda: Include a statement in the Export SOP regarding SOM (1301.74 (b)
- Overall SOM program and related procedures need annual review.
- Michele to reach out to NJ Pharm Industry Group to see what they do with chargeback data.
- Ursula/JOM/CSC/Nguyen -Rather than SLOB material, develop process that will allow a planned inventory movement to wholesalers. Concerta label changes result in these situations.
- Andres Lopez/Michele Dempsey - SOM Project needs to be prioritized and given a PM. Need to start January 2018.
- Debbie Sniscak to set up another workshop to review process with IT experts in January and determine IT path forward.

Comment [SB[16]: Yes]

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- Michele/Brian (Scott/Nguyen optional)– set up meeting with Commercial Excellence team in January to review what data is available and how we can use it for the program.